

**REMARKS**

Claims 1, 7–36, 41–43, and 46 are pending in this application. Non-elected claims 8–15, 17–20, 22–36, and 41–43 are withdrawn from consideration by the Examiner. By this Amendment, claims 2 and 3 are canceled. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

**I. Claim Objections**

The Office Action objects to claims 2 and 3 as being of improper dependent form for failing to further limit the subject matter of a previous claim. By this Amendment, claims 2 and 3 are canceled. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

**II. Rejections Under 35 U.S.C. §102**

**A. Perron**

The Office Action rejects claims 1–3, 7, 16, and 21 under 35 U.S.C. §102(b) as being anticipated by Perron et al. (1997) ("Perron"). By this Amendment, claims 2 and 3 are canceled, rendering their rejections moot. As to the remaining claims, Applicants respectfully traverse the rejection.

First, it is well settled that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Second, although an element may be inherently disclosed in a prior art reference, there is no anticipation by equivalents: every element must be literally present in the applied prior art reference. *Lawmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988). Third, in order to anticipate a claim, the prior art reference must also be enabling. The disclosure in an

assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003).

Claim 1 recites an "isolated nucleic acid molecule" and claim 7 recites an "isolated transcription product." The Office Action fails to establish and show where in the Perron reference it discloses an isolated nucleic acid molecule meeting the rest of the requirements of claim 1, or an isolated transcription product meeting the rest of the requirements of claim 7. The Office Action either completely ignores the claim limitation, which would make the rejection improper for not establishing a *prima facie* case of anticipation, or the Office Action implies that "extracted" is the same as "isolated."

If the latter be the case, Applicants respectfully request that the Office Action clearly indicates how it is construing the term "isolated" so that it may be clear on the record and so that the Applicants may appropriately respond to the rejection. However, Applicants also respectfully submit that one of skill in the art would recognize that simply extracting genetic material from a cell does not rise to the level of isolating a specifically-defined nucleic acid molecule or a specifically-defined transcription product.

Furthermore, as discussed above, although an element may be inherently disclosed in a prior art reference, there is no anticipation by equivalents: every element must be literally present in the applied prior art reference. The Office Action asserts that the claimed nucleic acid molecules are an inherent part of the nucleic acids referenced in the applied references. Although Applicants do not concede the point, the disclosures of Perron would not anticipate the claims even if the assertion of the Office Action is true. Even if the genetic material extracted in Perron inherently contained the claimed nucleic acid molecules or transcription products, the genetic material extracted in Perron is not inherently "isolated."

Finally, Perron does not enable one skilled in the art to obtain the isolated nucleic acid molecule of claim 1 or the isolated transcription product of claim 7. Without disclosure of the recited sequences in Perron, one of skill in the art cannot obtain and isolate the claimed compositions without undue experimentation. Because Perron is not an enabling reference, it cannot anticipate the claims.

For at least the reasons discussed above, Perron does not anticipate claims 1 and 7. Claims 16 and 21 depend from claims 1 and 7 respectively and, thus, also are not anticipated by Perron. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**B. Seifarth**

The Office Action rejects claims 1–3, 16, and 46 under 35 U.S.C. §102(b) as being anticipated by Seifarth et al. (1998) ("Seifarth"). By this Amendment, claims 2 and 3 are canceled, rendering their rejection moot. As to the remaining claims, Applicants respectfully traverse the rejection.

The arguments presented above with respect to Perron are equally applicable to Seifarth in that Seifarth fails to disclose an "isolated nucleic acid molecule" in accordance with claim 1, and fails to disclose the nucleotide sequences recited by claim 1, and fails to provide an enabling disclosure to obtain and isolate a nucleic acid molecule according to claim 1.

For at least these reasons, Seifarth does not anticipate claim 1. Claims 16 and 46 depend from claim 1 and, thus, also are not anticipated by Seifarth. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**III. Other Remarks**

The Office Action asserts that the specification does not exemplify or provide any indication that the sequence disclosed in SEQ ID NO:2 and encoding the amino acid of SEQ

ID NO:31 is not an inherent part of the human genome. However, precedential U.S. case law states:

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

*Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Applicants do not believe that this assertion of the Office Action, namely that the Applicants' own specification does not clearly establish that the recited sequences are not an inherent part of the human genome, is a basis in fact and/or technical reasoning that reasonably support the determination that the recited sequences are inherently present in the human genome.

Accordingly, Applicants respectfully submit that the Office Action does not establish a *prima facie* case of inherency.

Nevertheless, even if the recited sequences are inherently present in the human genome, the claims still are not anticipated by the applied references for at least the reasons discussed above. Moreover, the assertions made in the Office Action imply that an isolated nucleic acid molecule or an isolated transcription product that is otherwise inherently present in the human genome is unpatentable. Such a proposal appears to fly in the face of well-established case law and well-established examining procedures. For example, it is a common practice to recite the terms "isolated" and/or "purified" in the claims to help define the claimed subject matter as patentable subject matter, and to distinguish the claimed subject matter over a naturally occurring counterpart.

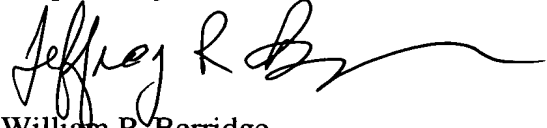
Thus, Applicants respectfully request that the Office Action indicates any case law or examining procedures that provide that the term "isolated" no longer sufficiently distinguishes claimed nucleotide or amino acid sequences from those inherently found in nature.

**IV. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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WPB:JRB

Attachment:

Petition for Extension of Time

Date: March 7, 2008

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